



CERTIFICATE OF ANALYSIS
Addendum
GemCell™ Fetal Bovine Serum
(Catalog Number 100-500)

Lot Number: A122065

Date of Manufacture: MAR2022

Product Expiry: MAR2027

Origin: United States

Storage Temperature: ≤ -10°C

For Cell Culture, further Manufacturing or Research use only. Not for direct Therapeutic use.

Product Description: *GemCell™ Fetal Bovine Serum is sterile-filtered through a 0.1 µm filter prior to freezing.*

Test	Methodology	Specification	Analysis
Biological Testing			
Endotoxin	LAL	<10.0 EU/mL	0.263 EU/mL
Hemoglobin	USP<90>	<20.0 mg/dL	15.67 mg/dL
Microbiological Testing			
Sterility	9CFR 113.26		
Bacteria		No Growth	No Growth
Fungi		No Growth	No Growth
Mycoplasma	PCR	Not Detected	Not Detected
Viral Testing			
	9CFR 113.53c [113.46, 113.47]		
Cytopathic Agents		Not Detected	Not Detected
Hemadsorbing Agents		Not Detected	Not Detected
Extraneous Viruses (FAb)			
Bluetongue Virus		Not Detected	Not Detected
Bovine Adenovirus		Not Detected	Not Detected
Bovine Parvovirus		Not Detected	Not Detected
Bovine Viral Diarrhea (Cytopathic)		Not Detected	Not Detected
Bovine Respiratory Syncytial Virus		Not Detected	Not Detected
Rabies Virus		Not Detected	Not Detected
Reovirus		Not Detected	Not Detected
Physical Testing			
Electrophoretic Pattern		Normal	Normal
Osmolality	Osmometer	260 – 350 mOsm/ kg	309.0 mOsm/kg
pH	pH meter	6.5 – 8.5	7.2
Biochemistry			
Albumin		Test and Report	1.5 g/dL
Alkaline Phosphatase	Chemistry Analyzer	Test and Report	250 IU/L
ALT (SGPT)	Chemistry Analyzer	Test and Report	14 IU/L
AST (SGOT)	Chemistry Analyzer	Test and Report	80 IU/L
GGT	Chemistry Analyzer	<10 U/L	2.0 IU/L



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Bilirubin, Total	Chemistry Analyzer	Test and Report	0.2 mg/dL
BUN	Chemistry Analyzer	Test and Report	15.0 mg/dL
Calcium	Chemistry Analyzer	Test and Report	14.1 mg/dL
Chloride	Chemistry Analyzer	Test and Report	95.0 mEq/L
Cholesterol	Chemistry Analyzer	Test and Report	29.0 mg/dL
Cortisol		Test and Report	<0.2 µg/dL
Creatinine	Chemistry Analyzer	Test and Report	2.6 mg/dL
Glucose	Chemistry Analyzer	Test and Report	142.0 mg/dL
IgG	ELISA	<0.300 mg/mL*	0.090 mg/mL
Insulin		Test and Report	4.9 uIU/mL
Iron, Serum	Chemistry Analyzer	Test and Report	167.0 µg/dL
Phosphorus	Chemistry Analyzer	Test and Report	10.2 mg/dL
Potassium	Chemistry Analyzer	Test and Report	13.5 mEq/L
Progesterone		Test and Report	<0.06 ng/mL
Protein, Total	Chemistry Analyzer	2.5 – 6.0 g/dL	3.7 g/dL
Sodium	Chemistry Analyzer	Test and Report	134.0 mEq/L
Testosterone		Test and Report	<0.01 ng/mL
T3		Test and Report	204.0 ng/dL
T4		Test and Report	15.0 µg/dL
Triglycerides	Chemistry Analyzer	Test and Report	75.0 mg/dL
Uric Acid	Chemistry Analyzer	Test and Report	2.7 mg/dL
Tetracycline		Test and Report	1.10 ng/mL

Our fetal bovine serum meets all USDA requirements and has passed ante and post-mortem inspection by a licensed veterinarian. It is collected in countries recognized as being free of foot-and-mouth disease and rinderpest. The origin of all fetal bovine serum is traceable by lot number, date, and country of collection. Precipitates may develop in this product upon freezing and/or thawing; this occurrence does not impact culture performance. *Some geographic regions may test higher than 0.300 mg/mL. If this be the case, refer to GGT results less than 10 U/L to ensure FBS purity. The testing that has been performed as part of this lot release has been reviewed by Quality Assurance personnel and has confirmed that the testing meets the specifications presented on this Certificate of Analysis.

Jaqueline Wilson
Name

13 DEC 2023
Date

QA Specialist
Title